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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/027,671	02/23/1998	ALAN K. SMITH	4292-0048-55	3507

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/027,671

Applicant(s)

SMITH ET AL.

Examiner

David A Saunders, PhD

Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): 112, first of claim 69.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 6, 7, 10-12, 38-41, 49-58 and 60-66.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

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CORRECTIONS RE OFFICE ACTION OF 8/1804:

At page 5, line 3 “hematoparetic” should be –hematopoetic--. At page 6, line 5 “line” should be –bone--.

REJECTIONS TO BE MAINTAINED:

Since the claims are unclear as to what is meant by “programmed to develop only into a specific type of cell” and since one thus cannot tell what applicant was describing, the 112, first and second paragraph rejections will be maintained. Also, since one cannot tell what this language encompasses, it will be considered that the claims encompass the prior art of record – i.e. the Caldwell et al and multiple Emerson et al references cited under 102(b).

While the amendment cancels certain claims and deletes certain recitations from pending claims that led to the confusion noted by the Office on 8/18/04, the amendment does not overcome. Confusion remains in light of applicant’s remarks at page 6. At the third paragraph, applicant states that the claims are limited to methods using cells “programmed to develop ONLY into a specific type of cell.” Applicant then points to page 7, lines 14-22 of the specification as providing examples of such. The examiner finds that this passage recites numerous of those cell types that were recited in the claims now cancelled or which have now been deleted in the claims now pending.

Applicant’s comment (page 6, para. 4) that “even if a T cell can develop into a CD4+ or a CD8+ cell, the T cell can still be programmed to develop into only one type of T-cell” points to more confusion. The notion of a “program” for the differentiation of a totipotent blastula cell into a pluripotent stem cell, then a multipotent cell, then to a “committed” cell, and finally to a differentiated cell is, by in large, merely a conceptual frame work for developmental biologists.

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At a few points along such a differentiation pathway one may be able to determine that certain genes have been activated, or that certain gene products (e.g. cell surface antigens) have appeared or disappeared; however, such knowledge does not tell one what the "program" is, in the same sense that one could obtain a computer program written to conduct a chemical process in an apparatus. Since one cannot determine what a T-cell's "program" might be, until after it has been effected (e.g. by the appearance of certain CD markers, secretion of certain lymphokines) it is not clear as to how one can know that a particular T-cell is or is not "programmed to develop only into a specific type of cell." For any given culture of T-cells, maintained at the density and with the medium replacement rate recited, one cannot tell whether or not the cells are "programmed". One would thus not know if the culturing of T-cells at the density and with the medium replacement rate recited does or does not infringe the claim. Metes and bounds are thus unknown. Since T-cells are among the best characterized cells, examiner's comments apply to any other type of cell encompassed by the claims.

CONTACTS

Any inquiry concerning this communication from the examiner should be directed to David A Saunders, PhD whose telephone number is 571-272-0849

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Typed 1/24/05 DAS



DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 1644